

Attorney Docket No.: **DEX-0054**
Inventors: **Robbins et al.**
Serial No.: **09/426,548**
Filing Date: **October 22, 1999**
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In the Claims:

Please amend the claims as follows:

9. (amended) An oligonucleotide probe complementary to a hMLH1 mutant 1, hMSH2 mutant 1, hMSH2 mutant 2, or hMSH2 mutant 3, said oligonucleotide probe hybridizing to hMLH1 mutant 1, hMSH2 mutant 1, hMSH2 mutant 2, or hMSH2 mutant 3.

REMARKS

Claims 2, 3 and 9 are pending in the instant application. Claims 2, 3 and 9 have been rejected. Claim 9 has been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of these amendments and the following remarks.

I. Rejection of Claims 2, 3, and 9 under 35 U.S.C. § 112, second paragraph

Claims 2, 3 and 9 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Examiner suggests that claim 9 is vague, unclear and confusing in the recitation of an

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"oligonucleotide probe to" hMLH and hMSH mutants because the metes and bounds for any characteristic of an oligonucleotide encompassed by the instant claims is not set forth. Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 9 to define the characteristics of the oligonucleotide probes. Specifically, claim 9 has been amended to state that the oligonucleotide probe is complementary to a hMLH1 mutant 1, hMLH1 mutant 2, hMSH2 mutant 1, hMSH2 mutant 2, or hMSH2 mutant 3 and that the oligonucleotide probe hybridizes to hMLH1 mutant 1, hMLH1 mutant 2, hMSH2 mutant 1, hMSH2 mutant 2, or hMSH2 mutant 3. Support for the amendment can be found in the specification at page 18, lines 1-3 and 17-26 and page 18, line 32 through page 19, line 19.

In the Advisory Action of August 13, 2002, the Examiner suggested that amendments made in the unentered response of August 1, 2002 raise issues under 35 U.S.C. § 112, second paragraph, because the metes and bounds of "hybridizing" and the size of "a portion" were not defined.

Amendments to the claims herein no longer contain the phrase "a portion".

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Further, with respect to the Examiner's suggestions regarding hybridizing being indefinite, Applicants respectfully disagree.

In accordance with MPEP § 2173.02, definiteness of claim language must be analyzed, not in a vacuum, but in light of:

- (A) The content of the particular application disclosure;
- (B) The teachings of the prior art; and
- (C) The claim interpretation that would be given by one possessing the ordinary level of skill in pertinent art at the time the invention was made.

Oligonucleotide probes for use in hybridization are well known and used routinely by those of skill in the art. See for example, U.S. Patent 5,591,826 submitted with the Information Disclosure Statement which teaches that DNA molecules which specifically hybridize to hMSH2 are typically at least about 20 nucleotides in length (col. 5, lines 26-30).

In addition, the application disclosure provides multiple examples of routine hybridization of oligonucleotide probes complementary to a hMLH1 mutant 1,

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hMSH2 mutant 1, hMSH2 mutant 2, or hMSH2 mutant at pages 17-18 so that one of skill in the art may accurately interpret the metes and bounds of these terms.

Further, the instant claims and application disclosure clearly set forth a standard by which an oligonucleotide probe of the present invention is determined - it must be complementary over a sufficient length so that the oligonucleotide probe hybridizes to hMLH1 mutant 1, hMSH2 mutant 1, hMSH2 mutant 2, or hMSH2 mutant. Thus, this is not a case of relative terminology such as set forth for the phrase "substantial portion" in MPEP § 21783.05(b)E, wherein there is no standard for measuring the degree intended. Instead one of skill in the art can clearly interpret the scope of the claims in light of the standard that the probe must hybridize with a specified mutant gene.

The MPEP and the case law are clear; when reviewing a claim for compliance with 35 U.S.C. § 112, second paragraph, the Examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. § 112, second paragraph. Claim 9 which includes a standard by which the scope of terms such

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as hybridizes can be determined clearly apprises one of ordinary skill in the art of its scope. Thus, this claim, as amended meets the requirements of 35 U.S.C. § 112, second paragraph.

Withdrawal of this rejection under 35 U.S.C. § 112, second paragraph is therefore respectfully requested.

II. Rejection of Claims 2, 3 and 9 under 35 U.S.C. § 102(b) and 35 U.S.C. § 102(e)

Claims 2, 3 and 9 have been rejected under 35 U.S.C. § 102(b) as being anticipated by Weber et al. These claims have also been rejected under 35 U.S.C. § 102(e) as being anticipated by Liskay et al. The Examiner suggests that Weber et al. and Liskay et al. teach hMLH1 mutant 2 and that claim 9 includes this mutant. Further, the Examiner suggests that claim 9 can reasonably be interpreted to encompass sequences which are not overlapping or complementary to the mutation specifically described, as discussed above in the 112 second paragraph rejection.

Accordingly, in an earnest effort to advance the prosecution of this case, Applicants have amended claim 9 to

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remove reference to the hMLH1 mutant 2. Further, as discussed in Section I, *supra*, claim 9 has been amended to state that the oligonucleotide probes are complementary to the mutant and hybridize to that mutant. Applicants believe this amendment overcomes the rejections of claims 2, 3 and 9 as being anticipated by Weber et al. and Liskay et al. Withdrawal of these rejections under 35 U.S.C. 102(b) and 35 U.S.C. §102(e) is therefore respectfully requested.

III. Conclusion

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "VERSION WITH

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MARKINGS TO SHOW CHANGES MADE."

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

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Please amend the claims as follows:

9. (amended) An oligonucleotide probe complementary
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hMSH2 mutant 3, said oligonucleotide probe hybridizing to
hMLH1 mutant 1, hMSH2 mutant 1, hMSH2 mutant 2, or hMSH2
mutant 3.